AMENDED CLAIMS

[received by the International Bureau on 15 February 2000 (15.02.00); original claim 1 amended; remaining claims unchanged (3 pages)]

1. A pharmaceutical composition for the treatment of acute disorders by sublingual administration, comprising an essentially water-free, ordered mixture of microparticles of at least one pharmaceutically active agent adhered to the surfaces of carrier particles, said particles being substantially larger than said microparticles and being water-soluble, and a bioadhesion and/or mucoadhesion promoting agent mainly adhered to the surface s of the carrier particles.

2. A composition according to claim 1, wherein the microparticles of said active agent or agents have a weight based mean diameter of less than 10 μm.

3. A composition according to claim 1 or 2, wherein the mean sieve diameter of the carrier particles is less than 750 μm, preferably then from 100 to 600 μm.

4. A composition according to any one of claims 1-4, wherein the carrier particles comprise a brittle material which will fragmentize easily when compressed.

5. A composition according to any one of claims 1-4, wherein the carrier particles contain from 0.1 to 25 weight percent of the bio/mucoadhesion promoting agent, preferably then from 1 to 13 weight percent, based on the total composition.

6. A composition according to claim 5, wherein the bio/mucoadhesion promoting agent is selected from the group consisting of acrylic polymers, cellulose derivatives, natural polymers having bio/mucoadhesive properties, and mixtures thereof.

7. A composition according to claim 6, wherein the bio/mucoadhesion promoting agent is selected from the group consisting of cellulose derivatives and comprising hydroxypropylmethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, sodium carboxymethyl cellulose, methyl cellulose, ethyl hydroxyethyl cellulose, carboxymethyl cellulose, microcrystalline cellulose and modified cellulose gum; crosscaramellose; modified starch; acrylic polymers comprising carbomer and its derivatives; polyethylene oxide;

chitosan; gelatin; sodium alginate; pectin; scleroglucan; xanthan gum; guar gum; poly-co-(methyl vinyl ether-maleic anhydride); and mixtures thereof.

8. A composition according to any one of claims 1-7, further comprising a pharmaceutically acceptable surfactant in a finely dispersed form and intimately mixed with the active agent or agents.

9. A composition according to claim 8, wherein the surfactant is present in an amount from 0.5 to 5 weight percent of the composition, preferably then 0.5 to 3 weight percent.

10. A composition according to claim 8 or 9, wherein the surfactant is selected from the group consisting of sodium lauryl sulfate, polysorbates, bile acid salts and mixtures thereof.

11. A composition according to any one of claims 1-10, wherein the carrier particles comprise a water-soluble, pharmaceutically acceptable carbohydrate and/or an inorganic salt.

12. A composition according to claim 11, wherein the carrier particles comprise at least one of the materials mannitol, lactose, calcium phosphate and sugar.

13. A composition according to any one of claims 1-12, wherein the carrier particles contain at least one pharmaceutical disintegrating agent promoting the dispersion of the microparticles of the active agent or agents over the sublingual mucosa.

14. A composition according to claim 13, wherein the disintegrating agent is selected from the group consisting of cross-linked polyvinylpyrrolidone, carboxymethyl starch, natural starch, microcrystalline cellulose, cellulose gum, and mixtures thereof.

15. A composition according to claim 13 or 14, wherein the disintegrating agent is present in an amount from 1 to 10 weight percent of the composition.

16. A composition according to any one of claims 1-15, wherein the pharmaceutically active agent is fentanyl or a pharmaceutically acceptable salt thereof.

17. A composition according to any one of claims 1-16, for the treatment of acute disorders by sublingual administration.

18. A composition according to claim 16, for the treatment of acute or breakthrough pain by sublingual administration of fentanyl or a pharmaceutically acceptable salt thereof.

19. A method for the treatment of acute disorders, wherein to an individual afflicted with said disorder is administered sublingually at least one dose unit of an essentially water-free pharmaceutical composition containing an effective amount of at least one pharmaceutically active agent in the form of microparticles adhered to the surfaces of carrier particles, which are substantially larger than said microparticles and are essentially water-soluble, and a bioadhesion and/or mucoadhesion promoting agent.

20. A metod according to claim 19, wherein the pharmaceutically active agent is fentanyl or a pharmaceutically acceptable salt thereof.

21. A method according to claim 20, wherein the fentanyl is administered in an amount from 0.05 to 20 mg, preferably then from 0.1 to 5 mg, per dose unit.